Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume VI Issue 8 October/November 2001

Proficiency Testing - Time to Enroll for 2002

by Leonard Kargacin

Proficiency testing (PT), as required under Medical Test Site (MTS) rule WAC 246-338-050, is a source of external quality control. This practice of testing unknown specimens from an outside source provides an additional means to assure quality laboratory testing results. Although labs perform daily internal quality control with their test systems, external quality control provides important interlaboratory comparisons to determine the accuracy and reliability of your testing procedures.

Between now and December is the time to enroll to be sure you receive PT samples in 2002. A listing of the currently approved PT programs, their phone numbers, and website addresses can be found on pages 3 & 4. Call the programs for a free copy of their 2002 PT brochure. If you are enrolled in PT for 2001, your current PT provider will automatically send you a PT order form and catalog for 2002. Remember, if you do not enroll quickly, you will not be guaranteed to receive samples for the first testing event that occurs between January-March 2002 and will receive 0% for non-participation. This is a failure, and may jeopardize your ability to continue testing patient specimens.

- Shop around for prices and test groups
- Enroll in more than one company if necessary to cover all tests

Information needed to enroll: Complete the 2002 Order Form in the PT brochure with the following information:

- Name (use the NAME **exactly** as it appears on your MTS license)
- Address
- CLIA ID # (our primary means of identifying your laboratory)
- MTS license number (see your MTS license)
- Select the appropriate program for your lab (you may have to enroll in several modules and/or companies to cover all analytes)

Release Results to LQA: All laboratories (including accredited laboratories) must indicate on the PT enrollment form that copies of your PT results must be sent to the Office of Laboratory Quality Assurance (LQA); **this must be done for each analyte!**

Regulated analytes:

- Regulated analytes (listed on page 3) must be covered by five sample modules shipped three times per year.
- Don't forget that non-waived tests for Influenza A and B must be covered by PT.

Dual complexity tests: Some manufacturers allow the users of certain waived tests the option of running the test as a moderate complexity test even though it had been granted waived status under CLIA (e.g. Roche Diagnostics allows this option for its CoaguChek users). This option is only available to users if it is specifically stated in the package insert. If the user performs the test as a waived test, they must follow the waived test requirements; if the user performs the test as a moderate complexity test, they must follow the requirements for moderate complexity tests. **NOTE:** If the laboratory chooses to perform the test as a moderate complexity test, it **must** participate in a **5-sample PT program three times per year** and must notify LQA of this decision.

Non-regulated analytes: All non-waived tests other than

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the regulated analytes found on page 3 must be tested using one or a combination of the following:

- A two-sample program from one of the proficiency testing providers
- Blind samples with known values
- Split samples with another lab
- Split samples with another instrument or method
- Two analysts perform microscopic tests and compare results
- Kodachromes of microscopic tests

Adding tests during the year:

- Notify our office within 30 days
- Enroll in PT for regulated analytes before you start testing patient samples and specify that results be sent to LQA

Deleting tests during the year:

- Notify our office within 30 days

Temporarily discontinuing tests during the year:

- Notify our office that the test was temporarily discontinued
- Indicate on PT form that test was not performed for this event using the code listed in your PT material
- Notify our office when the test is reinstated

Test Classification Website: The FDA has a new website available for looking up the complexity classification (waived, moderate, high) of test systems. The website address is:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

If you have other questions regarding proficiency testing, contact Leonard Kargacin at (206) 361-2804.

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"ELABORATIONS" is a free monthly publication of the Washington State Department of Health (DOH) Public Health Laboratories (PHL) and Office of Laboratory Quality Assurance (LQA).

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NOTE: Letters to the editor may be published unless specified otherwise by the author.

Website addresses:
DOH home page: http://www.doh.wa.gov
LQA home page:
http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

TIPS for Proficiency Testing Success

Improve your chances for successful participation in PT by considering the following suggestions:

√ **Notify PT provider** that copies of PT results for **each** analyte are to be sent to the Office of Laboratory Quality Assurance.

√ **Handle PT samples like patient samples:** Don't run them multiple times.

√ **Retain all raw data:** Save data showing the workup of PT samples, instrument printouts, worksheets, log sheets.

√ **Make sure all testing personnel perform PT during the year:** Share or rotate the samples among all staff that perform the test.

√ **Fill in the Method Code:** Do not leave blank.

√ **Correctly report the reason PT was not done:** If you are unable to test for some reason, indicate this on the answer sheet. If you discontinued testing for an analyte, indicate this on the sheet. Immediately notify LQA of any change.

√ **Be timely:** Always be sure to meet the deadline for returning your results.

√ **Review your graded results:** Review your graded PT results with your lab director. Document corrective action for scores below 80%. Evaluate ungraded results.

REGULATED ANALYTES:
These tests **MUST** be covered by PT

CHEMISTRY
ALT/SGPT
Albumin
Alkaline phosphatase
Amylase
AST/SGOT
Bilirubin, total (or neonatal)
Blood gas pO2, pCO2, pH
Calcium, total
Chloride
Cholesterol, total
HDL Cholesterol
Creatine kinase
Creatine kinase isoenzymes
Creatinine
Glucose
Iron, total
LDH
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

ENDOCRINOLOGY
Cortisol
Free Thyroxine
Serum Pregnancy (HCG)
(qualitative or quantitative)
T3 Uptake
Triiodothyronine
TSH
Thyroxine

TOXICOLOGY
Alcohol, blood
Blood lead
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide (and metabolite)
Quinidine
Tobramycin
Theophylline
Valproic Acid

HEMATOLOGY
Cell Identification
Auto or manual WBC differential
Erythrocyte Count (RBC)
Hematocrit (automated)
Hemoglobin
Leukocyte count (WBC)
Platelet Count
Fibrinogen
Partial thromboplastin time
Prothrombin time

IMMUNOHEMATOLOGY
ABO Group
D (Rh typing)
Antibody Detection
Compatibility testing
Antibody Identification

SYPHILIS SEROLOGY
RPR, VDRL, MHA-TP, etc.

IMMUNOLOGY
Alpha-1 antitrypsin
AFP (tumor marker)
Antinuclear antibody
ASO
HIV
Complement C3, C4
HBsAg, Anti-HBc, HBeAg
IgA, IgE, IgG, IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

BACTERIOLOGY
Cover the specialty according to the different types of testing performed

MYCOLOGY
Cover the specialty according to the different types of testing performed

PARASITOLOGY
Direct only
Concentration/Stain

VIROLOGY
Viral antigen detection
Viral culture
Viral FA
Other EIA for virus

MYCOBACTERIOLOGY
Cover the specialty according to the different types of testing performed

Approved Proficiency Testing Providers

Accutest	(800) 356-6788
Amer. Acad. of Family Physicians	(800) 274-7911
Amer. Assoc. of Bioanalysts	(800) 234-5315
American Proficiency Institute	(800) 333-0958
ASIM Medical Lab Evaluation	(800) 338-2746
California Thoracic Society	(714) 730-1944
College of American Pathologists	(800) 323-4040
EXCEL (CAP)	(800) 323-4040
Idaho Bureau of Laboratories	(208) 334-2235
Wisconsin State Lab. of Hygiene	(800) 462-5261

Accredited Laboratories - PT Notice

The Office of Laboratory Quality Assurance (LQA) now receives data from the proficiency testing (PT) providers electronically rather than by hard copy. While this is an efficient system, it is not without its own set of problems.

Two of the most common problems we are having with the accredited laboratories are not providing the PT providers with the correct CLIA and MTS number designations, and not authorizing the release of all PT results to LQA. Correction of these two common problems can be easily accomplished when enrolling/renewing your PT for 2002. Please follow the suggestions below.

Information that **must** be included on your PT enrollment or renewal form for 2002 includes:

- Facility Name (use the NAME **exactly** as it appears on your MTS license)
- MTS license number (see your MTS license)
- CLIA ID # (our primary means of identifying your laboratory) - see your MTS license
  NOTE: If your facility has multiple sites included under one MTS license, be sure that **all** PT results are referenced to the CLIA number for that license.
- **Release Results to LQA -** All accredited laboratories should indicate that copies of your PT results must be sent to the Washington State Department of Health Office of Laboratory Quality Assurance (LQA); **this must be done for each analyte! Attaching a note to your enrollment or renewal form stating that all PT results are to be released to the Washington State Department of Health will help to insure that this will occur.**

Test Classification Website: The FDA has a new website available for looking up the complexity classification (waived, moderate, high) of test systems. The website address is:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

NOTE: If you have already mailed in your PT renewal form, you will receive a confirmation of your order from the PT provider. Please return your confirmation to the PT company along with a note that copies of your PT results must be sent to the Washington State Department of Health Office of Laboratory Quality Assurance.

If you have any questions about PT, please contact the LQA office at (206) 361-2804.

Proficiency Testing Provider Websites

Accutest	www.accutest.org/index.html
AAB-American Association of Bioanalysts	www.aab.org
AAFP-PT-American Academy of Family Physicians	www.aafp.org/pt
API-American Proficiency Institute	www.api-pt.com
ASIM-American Society of Internal Medicine/MLE	www.acponline.org/mle/
Californina Thoracic Society	www.thoracic.org/chapters/state/california/ca.html
CAP-College of American Pathologists	www.cap.org
Idaho Bureau of Laboratories	None available at this time
Wisconsin State Laboratory of Hygiene	www.slh.wisc.edu/pt/index.html

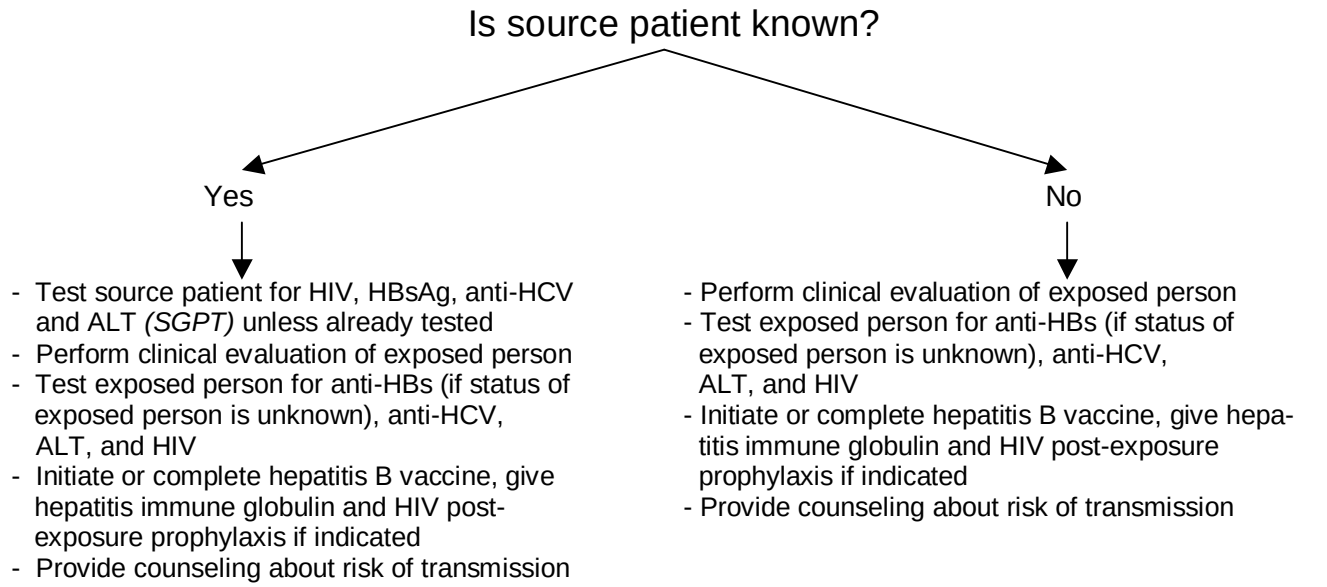
Exposure Guideline Update

The original Hepatitis Practice Guidelines were published in the January/February 2001 issue of *Elaborations* (Vol. VI, Issue 1). We received feedback from some of our readers indicating that CDC had just published an updated guideline for the "Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post Exposure Prophylaxis". The algorithm for Substantial Exposure Testing and Referral Guidelines has been updated to reflect these changes and can be found on pages 5 and 6. We appreciate the feedback given on the practice guidelines.

Substantial Exposure to Blood or Other Potentially Infectious Body Fluids

Washington State Clinical Laboratory Advisory Council to the Washington State Department of Health
September 2001

FOR EDUCATIONAL PURPOSES ONLY
The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.



HIV Protocol

Note: Refer to HIV Screening Guidelines for additional information

SOURCE	EXPOSED PERSON
HIV negative, source low risk	- HIV testing
	- No intervention
HIV positive, HIV negative but source high risk, or HIV status unobtainable	- Clinical evaluation
	- Consult CDC guidelines for prophylaxis
	- Test for HIV initially and again at 6 weeks, 3 months, and 6 months (at 12 months only if source is also infected with hepatitis C)

Hepatitis C Protocol

Note: Refer to Hepatitis C Management Guidelines for additional information

SOURCE	EXPOSED PERSON
Low Risk	- No intervention
High risk or anti-HCV positive	- Test for anti-HCV and liver function (ALT) initially and again at 4-6 months. May offer HCV by PCR testing at 4-6 weeks.

(Continued on next page)

Hepatitis B Protocol

Recommended post-exposure prophylaxis for percutaneous or permucosal exposure to hepatitis B virus, United States

Note: Refer to Acute Hepatitis Testing Guidelines & Chronic Hepatitis Guidelines for additional information

	Treatment when source is		
Vaccination and anti-body response status of exposed person	HBsAg positive	HBsAg negative	Source not tested or status unknown
Unvaccinated	HBIG[1] x 1; initiate HB vaccine series[2]	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated:			
Known responder[3]	No treatment	No treatment	No treatment
Known non-responder	HBIG x 2 or HBIG x 1 and initiate revaccination	No treatment	If known high-risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs 1. If adequate[3], no treatment 2. If inadequate[3], HBIG X 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate[3], no treatment 2. If inadequate[3], give vaccine booster and recheck titer in 1-2 months

* About 5% of people don't respond to the hepatitis B vaccine; most are over age 50 or obese. 50% of non-responders to the first series of vaccine (3 doses) will respond to a second full series of 3 doses. If a positive anti-HBs can't be shown after 3 to 6 doses (1 to 2 series), the person is considered a non-responder and not protected.

References:
1. Garb, James R. MD, Director, Occupational Health and Safety, Baystate Health Systems, Managing Body Substance Exposures, Nursing, 1996
2. JAMA 1999; 281: 931-36 (March)
3. Nursing Clinics of North America 1999; 34:213
4. CDC. Recommendations for Prevention and Control of Hepatitis C virus (HCV) Infection and HCV-Related Chronic Disease. MMWR 1998;47 (RR-19);1-39
5. CDC. Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States through Universal Childhood Vaccination: Recommendations of the ACIP. MMWR 1991;40 (RR-13);21-25
6. CDC. Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Post Exposure Prophylaxis. MMWR 1998;47 (RR-7);1-28
7. CDC. Hepatitis B Post-exposure Prophylaxis Recommendations MMWR 1997; (RR-18) p23 Table 3
8. CDC. Updated United States Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Post Exposure Prophylaxis. MMWR 2001;50 (RR-11); 1-42.

Reviewer:
1. Hofmann, Jo MD, Medical Director, Infectious Disease & Reproductive Health, WA State Department of Health

[1] Hepatitis B immune globulin; dose 0.06 mL/kg intramuscularly
[2] Hepatitis B vaccine
[3] Responder is defined as a person with adequate levels of serum antibody to hepatitis B surface antigen (i.e., anti-HBs $\geq$ 10 mIU/mL); inadequate response to vaccination defined as serum anti-HBs < 10 mIU/mL

INR: Points To Consider

The World Health Organization (WHO) introduced the International Normalized Ratio (INR) in 1983 in an attempt to standardize the prothrombin time (PT) reporting system. In light of events earlier this summer in Pennsylvania where two patients died after being incorrectly dosed based on their INR result, this article provides some hints to prevent such occurrences from happening in your facility.

INR Calculation: This INR formula is the Patient Prothrombin Time in seconds divided by the Normal Patient Reference Mean in Seconds raised to the power of the ISI value.

- The **ISI** (International Sensitivity Index) value is assigned by the manufacturer of the thromboplastin reagent. It can be found in the package insert of the thromboplastin reagent. The ISI is an indication of how sensitive the thromboplastin reagent is in relation to the standard set by the WHO.
- The **Normal Patient Reference Mean** is determined by calculating the geometric mean of at least 20 healthy individuals using that lot of thromboplastin.
- If the INR calculation is not properly set up, erroneous patient results may be reported.

In many of the new instruments such as the CoaguChek, the INR information is automatically adjusted (with no operator intervention required) with each new lot number of reagent. However, if your instrument does not do this automatically, the following are things you should consider:

- Blue top citrate blood drawing tubes are still available in two strengths (3.2% and 3.8%). However, NCCLS Guideline H21-A3 recommends that the 3.2% concentration tube be used for coagulation testing. The difference in citrate concentration will affect the PT results and, therefore, the INR results. Whatever citrate concentration a laboratory uses, they should always use that same concentration for patient testing once it has been put into use.
- To minimize the impact of changing reagent lot numbers frequently, ask your thromboplastin reagent manufacturer to sequester a lot number for you for at least one year.
- Record the reagent information (lot number, expiration date, date received, date opened, and ISI value) on a log sheet so that changes in the reagent lot number and ISI can be easily seen.
- When a new lot number of thromboplastin reagent is received, the normal patient reference mean must also be re-verified and changed if necessary. This value should be determined by calculating a geometric mean of at least 20 healthy individuals. NOTE: It is <u>not</u> acceptable to use the daily normal control value or the mean of the normal control range in place of the normal patient reference mean for your facility.
- Always check the thromboplastin package insert to confirm the ISI value. NOTE: ISI values are considered instrumentation specific, for example mechanical versus photo-optical.
- If you perform protimes using a manual system such as the fibrometer:
  - o Verify that you are using the correct formula to calculate the INR;
  - o Verify that the ISI used in your calculation matches that found in the package insert for the thromboplastin you are currently using;
  - o If you are using a chart from which to read the INR, make sure that it based on the current ISI value.
- Know where the INR is calculated (manually, analyzer, or LIS).
  - o Make certain that the INR calculation is properly turned on in your analyzer or LIS by following the procedure manual;
  - o Verify that the formula you are using is correct regardless of where is it calculated (manually, analyzer, or LIS);
  - o Periodically, manually calculate a patient INR value and compare with the instrument or LIS INR calculation to make sure that the values match.
- Make sure to enter the correct International Sensitivity Index (ISI) value from the package insert of your PT reagent into your instrument or laboratory information system (LIS). If the product lot number changes, then the new ISI value must be entered.
- Some manufacturers provide a chart from which to read the INR values that is based on the lot number of thromboplastin in use and your normal patient reference mean. For each new reagent lot number, make sure that the INR values from the chart are representative of the normal patient reference mean that you obtained using that lot number.
- When you receive a new lot number of thromboplastin reagent, run several patients (minimum of 5-10) in parallel with the old lot number and with the new lot number of reagent (record both the seconds and the INR).
- After instrument repairs, software upgrades or preventative maintenance, verify that none of the INR parameters (ISI and normal patient reference mean) have been altered.
- Record INR values along with the PT in seconds on your daily quality control specimens. This will alert you to any of the above changes that might impact your INR values.

Following these recommendations will help improve the processes in your laboratory and ensure the delivery of more accurate test results to physicians.

Still Time to Register!

8th Annual Clinical Laboratory Conference

November 12, 2001

Seattle Marriott Sea-Tac Hotel

Contact Leonard Kargacin at (206) 361-2804 or leonard.kargacin@doh.wa.gov for registration information.

Calendar of Events

8th Annual Clinical Laboratory Conference
November 12, 2001 Seattle

WSSCLS/NWSSAMT Spring Meeting
April 25-27, 2002 Everett

Northwest Medical Laboratory Symposium
October 2002 Portland

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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